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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,077	02/14/2001	Jonathan S. Stamler	1661 - CIP	9791

7590 10/31/2002

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/31/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/782,077

Applicant(s)

Stamler

Examiner

John Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 16, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-9 are pending in this application.

Applicant's election with traverse of NOCl as the single disclosed species in Paper No. 5 (7/16/02) is acknowledged. The traversal is on the ground(s) that the Office action is treating the requirement as a restriction requirement rather than an election of species requirement. This is not found persuasive because the requirement is indeed an election of species.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is advised of the following: claimed subject matter directed to the species NOCl and N₂O₃ could be deemed allowable **except** for the double patenting rejection set forth below.

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,314,956. Although the conflicting claims are not identical, they are not patentably distinct. The patented claims do not explicitly recite NOCl or N₂O₃, but such compounds are suggested from the language, "compound having an NO group." Both NOCl and N₂O₃ are well known to have an NO group, and one having ordinary skill in the art would have been motivated to utilize such readily available NO group containing compounds to treat pulmonary disorders, as claimed. Therefore, the ordinary skilled artisan in this field would have recognized the subject matter of claims 1-5 as an obvious variation of the subject matter of the patented claims.

The examination of this application will now continue with the next species, H₂S.

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Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-3, 6-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other gaseous active agents, does not reasonably provide enablement for H₂S. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims with respect to H₂S.

The state of the art regarding H₂S is such that one skilled in the art would not readily accept effective treatment of pulmonary disorders of the type claimed herein. The pulmonary disorders encompassed by the claims include asthma (specification p. 3, first paragraph). Embase abstract 2000083448 discloses that some asthmatics may demonstrate signs of bronchial constriction as a result of exposure to 2 ppm H₂S for 30 minutes. Chemical abstracts 115:56107 discloses that asthmatic persons exposed to low concentrations of H₂S demonstrated increased airway resistance and decreased specific airway conductance. One asthmatic patient experienced bronchial obstruction. Medline abstract 92296647 discloses that H₂S exposures at concentrations below the current occupational limits cause physiological changes in pulmonary function, thus suggesting that asthmatics are at risk. Applicant's Example X is noted in this regard, but (i) it is not clear how much/what effect the H₂S is having there due to the several other combined treatments that are applied, and (ii) it is not clear from Example X whether H₂S

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itself has treatment efficacy, against the countervailing expectation of the state of the art as set forth above. Insufficient information has been provided as to the specifics of the protocol and the isolation of the effect of H₂S, in light of the state of the art evidence to the contrary.

For these reasons, all claims must be rejected.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOHN PAK
PRIMARY EXAMINER
GROUP 1600